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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,228	06/29/2005	Keiji Hasumi	05360/HG	4548
1933 7590 05/30/2007 FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 220 Fifth Avenue 16TH Floor NEW YORK, NY 10001-7708			EXAMINER KOSAR, AARON J	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 05/30/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/541,228

**Applicant(s)**

HASUMI ET AL.

**Examiner**

Aaron J. Kosar

**Art Unit**

1609

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>29 JUN 2005</u>   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Information Disclosure Statement*

The information disclosure statement filed June 29, 2005 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically, SHIMIZU and HASUMI have not been provided.

JP 2002-272453 A has been considered to the extent of the provided English Language Abstract.

### *Claim Objections*

Claim 3 is objected to because of the following informalities: *substate* appears to be a typographical error of *substrate*. Appropriate correction is required.

### *Claim Rejections - 35 USC § 101*

#### 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

**Claims 1 and 2** are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claim as written reads upon *naturally occurring compositions*, including membrane-bound proteins, such as receptor tyrosine kinases (RTK) systems, which have a support (cell membrane) bound to an enzyme (RTK), a molecule (protein tyrosine phosphatase, PTP), and substrate (tyrosine)(*e.g.* see ÖSTMAN, page 258 (Östman, *et al.* *Trends in Cell Biology*, 2001, 11(6),258-266).

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The claims also read upon a naturally-occurring, tissue-type plasminogen activator (tPA) mediated plasminogen ensemble, which has a lysine-dependent tPA-to-cell surface binding mechanism, and mediates surface-bound plasmin generation from plasminogen (*e.g.* see BIZIK and VAHERI, *Pathophysiology*, 1998, 5(Supplement 1), 139).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-4** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The “affinity trap reactor” is claimed to comprise a structural relationship of a) a support, b) a support bound with an enzyme, c) a molecule, and d) binding with a substrate of the enzyme. It is unclear whether the substrate is required or how the components are interconnected to each other and to the support. Several reasonable combinations are possible (*e.g.* a support bound with an immobilized enzyme and a free molecule, a support bound with each of an immobilized enzyme and an immobilized molecule, etc).

Additionally, claims to the structural relationship of the single-stage process elements a') a support, b') bound bacillolysin MA, and c') lysine also may be interpreted in multiple reasonable configurations, such as having a free or bound lysine, having various connectivities of elements (a')-(c'), etc.

Each combination describes a distinct and materially different apparatus requiring significantly divergent methods of production, having distinct functions, and each apparatus

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would hold a different status in the art. As such it would be unclear to a person of skill how to determine the structural relationships, rendering the claims indefinite.

**Claim 4** is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: an active result step, having support from the original disclosure and expressing the claimed steps of contacting/reacting the elements including the transition which correlates a concluding active step bridging to the BL-angiostatin product obtained. As such it would be unclear to a person of skill how to determine the omitted essential steps, rendering the claim indefinite.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as being anticipated by ÖSTMAN (*Trends in Cell Biology*, 2001, 11(6), 258-266), McCLUNG (McClung, W.G., *et al. Journal of Biomedical Materials Research*. 2000,49(3), 409-414), PATEL (U.S. Patent 5,227,297), FISCHER (U.S. Patent 6,228,613), or RÖMISCH (U.S. Patent 6,528,299).

The claims recites a composition comprising an enzyme-linked support and a molecule that binds with the enzyme's substrate; however, Östman teaches these features by describing membrane-bound proteins, such as receptor tyrosine kinases (RTK), which have a support (cell membrane) bound to an enzyme (RTK) and a molecule (protein tyrosine phosphatase, PTP) that binds to the RTK substrate (tyrosine)(Östman, page 258, ¶1,2).

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McClung anticipates the claims by motivating tPA binding to a surface through lysine moieties, the binding of plasminogen to lysine, and the conversion of plasminogen to plasmin via a plasminogen/plasmin complex bound to a lysine-rich support surface (McClung, conclusion, page 414).

Patel teaches a protease (tPA), a support and molecule that binds with the substrate (the solid support satisfies both), and the enzyme's substrate ("-X-Y-Arg") (Patel, column 1, lines 23-32; column 2, Summary).

Römisch teaches a chromatographic system that employs a substrate that immobilizes heparin/heparin-related compounds. These compounds also bind to protease and/or proenzyme giving the compounds dual status as both the linker and the enzyme's substrate (Römisch, column 2, ¶4).

Fischer teaches an organizational interrelationship of the components similar to Römisch, Fischer describing a chromatographic system that uses a heparin affinity chromatography (substrate, lysine; support, Sepharose) to selectively bind to plasma protease (Fischer, column 16, Example 7).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and has been entered into the PTO-892 form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron J. Kosar whose telephone number is (571) 270-3054. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

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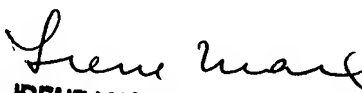
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ajk/

Aaron Kosar

Examiner, Art Unit 1609

  
**IRENE MARX**  
**PRIMARY EXAMINER**